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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,324	07/08/2003	Norikazu Ueyama	OKA-0209	7360
23353	7590	11/16/2005	EXAMINER	
RADER FISHMAN & GRAUER PLLC LION BUILDING 1233 20TH STREET N.W., SUITE 501 WASHINGTON, DC 20036			LEARY, LOUISE N	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/614,324

Applicant(s)

UEYAMA ET AL.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10-6-2003</u> | 6) <input type="checkbox"/> Other: ____  |

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1. Claims 1-16 are pending in this application.
2. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-16 are indefinite because in all occurrences, the phrase "capable of" does not recite a definite bond reaction.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- I, Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gariepy (WO 93/23425, 1993).

Gariepy discloses a metal chelating peptide complex "[...comprising a carboxy-terminal portion having 3-6 amino acid residues, wherein only the amino acid residue adjacent to the C-terminal residue has a reactive group for unidirectionally and selectively coupling the peptide to a targeting molecule; and a branched N-terminal portion having 4-16 amino groups to which are coupled metal chelating polydentate ligands.]" Also, Gariepy discloses the reactive group of the peptide described above is an activated ester. See page 13-15.

II. Claims 1-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Anderson et al (5,439,829)(August 1995).

Anderson et al disclose metal complexes identical or closely analogous to the instantly claimed metal complexes. Anderson et al specifically disclose "[A chelating agent is covalently bonded to a biologically active molecule such as an enzyme or antibody, the biologically active molecule is contacted with a support containing a bound transition metal ion whereby the metal ion is chelated by the chelating agent and oxidation state of the metal ion is changed by treatment with an oxidizing or reducing agent to provide a kinetically inert: oxidation state to immobilize the biologically active molecule on the support. The transition metal ion is preferably Co(II), Cr(II) or Ru(III) and the oxidation state of the metal ion is changed to Co(III), Cr(III) or Ru(II), respectively. The chelating agent can be iminodiacetic acid, nitrilotriacetic acid, terpyridine, bipyridine, triethylenetetraamine, biethylenetriamine, 1,4,7-triazacyclonane

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or chelating peptide.]" See the abstract. Also, Anderson et al disclose "[...a). preparing a kinetically labile transition metal complex with a transition metal and 2 or more of the same or different of said chelating agents, and b.) changing the oxidation state of said metal ion to form the kinetically inert transition metal complex.]" Note column 8, lines 9-21. Regarding the limitations of instant claim 5, Anderson et al disclose "[Organic Chelating Agent- bidentate, tridentate, quadridentate, tripod and macrocyclic ligands such as iminodiacetic acid, nitrilotriacetic acid, terpyridine, bipyridine, triethylenetetraamine, biethylene triamine.]" See column 6, lines 50-53. With respect to the claim limitations reciting "functional group capable of forming the covalent bond with the amino acid of the N-terminal amino acid residue", Anderson et al disclose the use of nucleotides and ester forming groups. In addition, Anderson et al disclose chemical formulae that represent identical compounds and/or compounds that are closely analogous to the compounds claimed in the present invention. See columns 8-15, 28-29 and columns 78 and 79. In regards to the reagent of instant claim 14, Anderson et al disclose reagents comprising a metal complex that is identical or closely analogous to the instantly claimed metal complex. Further, Anderson et al disclose methods of claims 15 -16, Anderson et al disclose using the metal complexes in assay systems and protein protocols. Note the abstract and columns 2-14.

Thus, Anderson et al disclose the invention claimed except for the stating the "coordination number thereof is 2, 3, 4, 5, or 6".

However, regarding the "coordination number thereof is 2, 3, 4, 5, or 6", Anderson et al disclose "[...the oxidation state of the metal ion is changed by treatment

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with an oxidizing or reducing agent to provide a kinetically inert: oxidation state to immobilize the biologically active molecule on the support. The transition metal ion is preferably Co(II), Cr(II) or Ru(III) and the oxidation state of the metal ion is changed to Co(III), Cr(III) or Ru(II), respectively. The chelating agent can be iminodiacetic acid, nitrilotriacetic acid, terpyridine, bipyridine, triethylenetetraamine, biethylenetriamine, 1,4,7-triazacyclonane or chelating peptide.]” Again, see the abstract. Hence, Anderson et al disclose the invention as claimed and addresses the inherent coordination number property for the metal complex which anticipates or renders obvious the invention as claimed.

The burden of proof is on applicants to show patentably distinct differences between the Anderson et al disclosure and the invention as presently claimed.

4. The Bower et al reference (US Patent 5,705,143) has been cited to further show the state of this art.


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
LOUISE N. LEARY  
PRIMARY EXAMINER

November 11, 2005